Amendment dated October 29, 2008 Reply to Office Action of April 29, 2008

## **AMENDMENTS TO THE CLAIMS**

Docket No.: 64734(70403)

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

- 1. 61. (Cancelled)
- 62. (Currently amended) A method of treating premature ejaculation in a male comprising administering to the male an antidepressant via a route selected from the group consisting of:
  - i) mucosal administration;
  - ii) administration to the lungs
  - iii) local administration to at least a part of the male genitalia and
  - iv) a combination of two or more of mucosal administration, administration to the lungs and local administration to at least a part of the male genitalia.
- 63. (Currently amended) A method according to claim 4 62 wherein the antidepressant is administered prior to or during sexual activity.
- 64. (Currently amended) The method according to claim 1–62 wherein the mucosal administration is by nasal administration, buccal administration, rectal administration or combinations thereof.
  - 65. (Cancelled)

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66. (Currently amended) The method according to claim <u>1-62</u> wherein local administration is directly to the penis.

- 67. (Cancelled)
- 68. (Cancelled)
- 69. (Currently amended) The method according to claim <u>62</u>, wherein the antidepressant is administered in an amount of between 0.1 and 1000 mg per dose.
- 70. (Currently amended) The method according to claim 1–62 wherein a single antidepressant or single combination of antidepressants is administered by two or more routes selected from the via the combination of mucosal administration, administration to the lungs and local administration to at least a part of the male genitalia.
- 71. (Currently amended) The method according to claim 4–62 wherein two or more different antidepressants or two or more different combinations of antidepressants are administered by two or more routes selected from the via the combination of mucosal administration, administration to the lungs and local administration to at least a part of the male genitalia.
- 72. (Currently amended) The method according to claim 10-71 wherein the antidepressant combination includes serotonin reuptake inhibitor (SSRIs) and a monoamine oxidase inhibitor.
- 73. (Currently amended) The method according to claim 1–62 wherein the antidepressant is massaged into the skin of the male genitalia prior to intercourse for about one minute.

74. (Currently amended) The method according to claim 12-73 wherein the antidepressant is massaged into the skin of the male genitalia about 30 to 60 minutes prior to intercourse.

- 75. (Currently amended) The method according to claim 1–62 wherein the antidepressant is taken nasally within 30 minutes prior to intercourse.
- 76. (Currently amended) A composition for the treatment of premature ejaculation, said composition comprising an antidepressant formulated for mucosal administration, administration to the lungs and/or and local administration to at least part of the male genitalia.
- 77. (Currently amended) The composition according to claim  $\frac{15-76}{15}$  wherein said antidepressant is selected from serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, monoamine oxidase inhibitors, norepinephrine dopamine reuptake inhibitors, serotonin antagonist and reuptake inhibitors, norepinephrine antagonist/serotonin antagonists, synthetically derived phenylpiperazine antidepressants, antagonists of central L2- $\alpha$ 2 auto and heteroadrenoceptors, and mixtures thereof.
- 78. (Currently amended) The composition according to claim <del>15-76</del> wherein said antidepressant is a mixture of a serotonin reuptake inhibitor and a monoamine oxidase inhibitor.
- 79. (Currently amended) The composition according to claim 47–77 wherein said serotonin norepinephrine reuptake inhibitor is a bicyclic, tricyclic or tetracyclic antidepressant.
- 80. (Currently amended) The composition according to claim <u>15-76</u> wherein said antidepressant is selected from paroxetine, fluoxoetine, sertraline, citalopram hydrobromide, fluvoxamine, sertraline, nortriptyline hydrochloride, clomipramine hydrochloride, dothiepin hydrochloride, Imipramine hydrochloride, mianserin hydrochloride, amitriptyline hydrochloride, phenelzine sulphate,

tranylcypromine sulphate, isocarboxazid, moclobemide, serotonin and/or adrenalin update inhibitors such as venlafaxine, nefazodone hydrochloride, trazodone, bupropion, mirtazapine, doxepin hydrochloride, trimipramine or mixtures thereof.

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## 81. (Cancelled)

- 82. (Currently amended) The composition according to claim <u>45-76</u> further including an enhancer agent selected from cyclodextrin, water, a monohydric alcohol, <u>and a polyhydric alcohol.</u>
- 83. (Currently amended) The composition according to claim <u>15-76</u> comprising:

about 20 to about 60% water;

about 80% to about 40% alcohols

1 to 10% Hydroxypropyl-β-cyclodextrin (HPBCD) and wherein antidepressant agent and the HPBCD are typically-present in the composition in a molar ratio of about 1:0.8 to 1:1.4 respectively.

- 84. (Currently amended) The composition according to claim <del>15</del>-<u>76</u> wherein the concentration of the antidepressant is between about 1 to 10% by weight of said composition.
- 85. (Currently amended) A kit comprising at least two of: an antidepressant formulated for nasal administration; and an antidepressant formulated for local administration to at least part of the male genitalia and an antidepressant formulated for administration to the lungs.